# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy

### Protocol summary

**Study aim**
Comparison of the effect of local marcaine (site of ports) with intraperitoneal marcaine on pain after laparoscopic cholecystectomy surgery.

**Design**
Clinical trial without control group, with parallel groups, one-sided blind, randomized, phase 2-3 on 28 patients, rand function of Excel software was used for randomization.

**Settings and conduct**
Patients in Aria Hospital of Mashhad will be randomly divided into two groups with the help of sealed envelopes: Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria : 1- Patients undergoing elective laparoscopic head cystectomy surgery 2- Age between 18 and 65 years Exclusion criteria: 1- The occurrence of unwanted complications during the operation 2- People with contraindications to the prescription of anesthetic drugs or opioids (patients with known hypersensitivity to the compounds of various anesthetic drugs)

**Intervention groups**
Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.

**Main outcome variables**
1- Postoperative pain is different in the two study groups. 2- The amount of additional pain relief after the operation is different in the two study groups.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230526058293N1**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

**Registration date**
2023-05-31, 1402/03/10

**Registrant information**

**Name**
Shabnam Shafiee jafarabad

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3867 2305

**Email address**
shbnmshafiee@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-06-22, 1402/04/01

**Expected recruitment end date**
2023-08-23, 1402/06/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy

**Public title**
Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients undergoing elective laparoscopic head cystectomy surgery Age between 18 and 65 years
**Exclusion criteria:**
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **28**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients will be randomly divided into two groups with the help of sealed envelopes Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
This study will be conducted in the form of a two-group, single-blind clinical trial, where the patients will be unaware of the assigned treatment, on patients undergoing elective laparoscopic cephalocystectomy surgery at Aria Hospital in Mashhad. People with entry criteria and those without exit criteria will enter the study after providing an explanation about the design and completing the informed consent form. Patients will be randomly divided into two groups with the help of sealed envelopes Group 1: Local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the procedure before closing the wound, which will be 5 ml per port. Group 2: After removing the gallbladder, they will receive intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committee of Islamic Azad University, Mashhad.
**Street address**
Mashhad, Imam Khomeini Boulevard, Bazarche Sarab, between 13 and 15 Bazarche Sarab
**City**
mashhad
**Province**
Razavi Khorasan
**Postal code**
9187147578
**Approval date**
2022-10-01, 1401/07/09
**Ethics committee reference number**
129.IR.IAU.MSHD.REC.1401

## Health conditions studied

### 1

**Description of health condition studied**
Comparison of the effect of local marcaine (port location) with intraperitoneal marcaine on painafter laparoscopic cholecystectomy
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
The amount of pain after the operation
**Timepoint**
4-8-24 hour
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group Group 2: After removal of the gallbladder, intraperitoneal infiltration of 20 ml of 0.25% bupivacaine solution in the bed of the gallbladder and under the right dome of the diaphragm.
**Category**

Treatment - Surgery

**2**

**Description**
Control group: Intervention group: Group 1: local infiltration (port site) of 20 ml of 0.25% bupivacaine solution at the end of the operation before closing the wound
**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Aria hospital mashhad
**Full name of responsible person**
Dr.Hamed beyzaee
**Street address**
Mashhad - Jahanbani Street - Eastern Golestan Crossroads
**City**
mashhad
**Province**
Razavi Khorasan
**Postal code**
9187147578
**Phone**
+98 51 3222 9098
**Email**
nfo@aria-hospit.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Tooraj zandbaf
**Street address**
East golestan st 4, mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9187147578
**Phone**
+98 51 3222 9096
**Email**
nfo@aria-hospital.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Islamic Azad University
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Shabnam shfieejafarabad
**Position**
Medical student
**Latest degree**
Medical doctor
**Other areas of specialty/work**
General Practitioner
**Street address**
No 29 . daneshamooz st 6, mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9188869864
**Phone**
+98 51 3768 2305
**Email**
shbnmshafiee@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Mohammad javad ghamari
**Position**
Medical doctor
**Latest degree**
Specialist
**Other areas of specialty/work**
General Surgery
**Street address**
East golestan5 , mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9187147578
**Phone**

+98 51 3222 9096

**Email**

ghamarimj@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Shabnam shafiee jafarabad

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No 29, daneshamooz st 6, mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188869864

**Phone**

+98 51 3768 2305

**Email**

shbnmshafiee@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available